K113648

Summary of Safety and Effectiveness

Sponsor:	***aap* Implantate AG** Lorenzweg 5 D-12099 Berlin Germany
Company Contact:	Dipl.-Ing. Marc Seegers Phone:+49-30-750-19 -192 Fax: +49-30-750-19 - 111
Date	December 5, 2011
Trade Name:	*aap* LOQTEQ® Large Fragment Set
Common Name:	Large Fragment Set
Classification:	
Classification Name and Reference:	21 CFR 888.3030 Single/multiple com-ponent metallic bone fixation appliances and accessories – Class II and 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener - Class II
Device Product Code and Panel Code:	Orthopedics/87/ HRS: Plate, Fixation, Bone Orthopedics/87/ HWC: Screw, Fixation, Bone
Predicate device:	Large Fragment LCP Instrument and Implant Set of Synthes (USA) under the premarket notification K000682 (May – 1, 2000). At this time the system was called Synthes Large Fragment Dynamic Compression Locking (DCL) System.
Device Description:	Bone plates and screws are used for fixation of bone fragments, i.e., for treatment of bone fractures and other bone injuries. Bone plates are fixed by the use of bone screws. Bone plates and bone screws are implants. If the plates are used in conjunction with locking screws, a so called internal fixator will be realized (internal fixation).The LOQTEQ® Large Fragment Set consists of: • LOQTEQ® Narrow Plate 4.5, • LOQTEQ® Broad Plate 4.5, • LOQTEQ® Cortical Screw 4.5, T25, self-tapping • Cortical Screw 4.5, self-tapping • Set of Instruments, Large Fragment Set
Material:	Plates are made of cp Titanium (ASTM F67 or ISO 5832-2) Screws are made of Ti6Al4V (ASTM F136 or ISO 5832-3)

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Indications:

The aap LOQTEQ® Large Fragment Set is intended for: Fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

Substantial Equivalence:

The Substantial Equivalence of the new device and the predicate device is based on similar intended use, design, functionality, components and materials in use.

Documentation including mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.

Performance Data (Non-Clinical and / or Clinical):

Non-clinical tests have been performed and show the effectiveness and safety of the device.

Summary of Non-clinical tests:

Type of test:
Static and dynamic 4-point-bending test of bone plates according to ASTM F 382-99.

Assessment of test results:
Substantial equivalence with respect to the mechanical performance of the aap plates could be stated due to the test results gained. The subject device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Documentation regarding the mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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aap Implante AG
% Mr. Marc Seegers, Dipl.-Ing., Director QA/RA
Lorenzweig 5
D-12099 Berlin Germany

Re: K113648
Trade/Device Name: aap LOQTEQ Large Fragment Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 13, 2012
Received: August 15, 2012

Dear Mr. Seegers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113648

Device Name: LOQTEQ® Large Fragment Set

Indications for Use:

The *aap* LOQTEQ® Large Fragment Set includes Narrow and Broad Plates 4.5. The plates accept 4.5 mm locking screws and 4.5 mm cortical screws.

The *aap* LOQTEQ® Large Fragment Set is intended for:
Fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

 510(k) Number K113648